UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,735	02/16/2005	Michel Steiger	RE/3-32620A	1584

1095 7590 10/31/2007

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
KAROL, JODY LYNN	
ART UNIT	PAPER NUMBER
4133	

MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,735	STEIGER, MICHEL	
	Examiner	Art Unit	
	Jody L. Karol	4133	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/7/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 of PCT/EP03/09302 International Filing Date: 8/21/2003, which claims priority to EP 02018772.0. Claims 1-14 have been cancelled and claims 15-30 have been added as per applicant's preliminary amendment dated 2/16/2005. Accordingly, claims 15-30 are pending and examined on the merits herein.

Information Disclosure Statement

1. The information disclosure statement (IDS) filed on 7/7/2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on Application No. 02018772.0 filed with the European Patent Office on 8/22/2002.

Specification

3. The abstract of the disclosure is objected to because of the use of legal phraseology "said" in the second line. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that

the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if

the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is dependent on a cancelled claim. However, this appears to be a typo, and claim 16 is treated as dependent on claim 15 for examination purposes. If examiner is in error, the applicant is encouraged to address this matter.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-23 and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asche et al. (US 4,917,886).

The instant claims are directed to a pharmaceutical composition for topical use, wherein the composition is an opaque emulsion-gel, is completely devoid of an anti-fungal drug, and comprises diclofenac sodium salt, water, at least one C_2-C_4 alkanol, a

glycol solvent selected from the group consisting of propylene glycol and polyethylene glycol (200-20,000), at least one gelling agent selected from the group consisting of carbomers, at least one lipid, at least one nonionic surfactant, and a basic agent selected from the group consisting of ammonia, sodium hydroxide, potassium hydroxide to adjust the pH of the total composition to 6.5-8. It is noted that component (c) may or not be present because the range encompasses zero.

Claims 15, 16 as best understood (see rejection under 35 U.S.C. 112, second paragraph above), 20-23, 25, and 27-30 are interpreted as broad and open-end by virtue of the term "comprising." Claims 17-18 interpreted as analogous to claims 15 and 16. The phrase "consists essentially of" limits the scope of the claims to the specified materials or steps "and those that do not affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). However, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355. Claim 19 is interpreted as closed-ended by virtue of the phrase "consists of."

Asche et al. teaches topical compositions containing the following components in the following approximate ranges (see abstract):

i. 0.1-10% by weight of an anti-inflammatory active compound having at least one acidic group, such as diclofenac sodium as claimed in the instant claims 15-30 (see column 7, lines 45-54);

ii. 10-50% by weight of a C_2-C_4 alkanol as claimed in the instant claims 15, 17, 20-23, and 26-30, such as ethanol or especially isopropanol, or mixtures thereof, as claimed in the instant claims 16, 18 and 25 (see column 3, lines 58-62);

iii. 3-50% by weight of a lipid or mixture of lipids as claimed in the instant claims 15-26 and 29-30, such as parrafins, isopropyl myristate, or fatty acid esters such as caprylic/capric acid esters of fatty alcohols having 12 to 18 carbons, among several others as claimed in the instant claims 27-28 (see columns 4-5, and specifically column 4, line 22, and column 5, lines 17-31);

iv. 0.5-2% by weight of a gel structure former (gelling agent), such as polyacrylate (carbomer) as claimed in the instant claims 15-25 and 27-30 (see column 7, lines 5-14), and specifically acrylic acid polymerisate, Carbopol® 934 P, which is analogous to carbomer 934 as claimed in the instant claim 26 (see column 2, line 57 to column 3, line 7);

v. 1-20% by weight of a co-solvent, such as polyethylene glycol (200-6,000) or propylene glycol (200-6,000 units) as claimed in the instant claims 15-30 (see column 3, line 66 to column 4, line 7);

vi. 40-80% by weight of water as claimed in the instant claims 15-30;

vii. 0.5-5% by weight of an emulsifier provided the lipid phase is not self-emulsifying, such as a non-ionogenic (nonionic) surfactant as claimed in the instant claims 15-28 and 30 (see column 5, lines 54-56), and

specifically polyethylene ethers of fatty alcohols having 2 to 23 ethylene oxide units as claimed in the instant claim 29 (see column 6, lines 23-27); and

viii. optionally non-essential constituents, for example bases such as sodium salts, potassium salts, and ammonia as claimed in the instant claims 15-30 (see column 9, lines1-5, and column 7, lines 51-57).

wherein the composition has a pH of approximately 5 to approximately 7.5, and combines the properties of a gel and an oil/water emulsion (see column 1, lines 30-61). Asche et al. further teaches that a base may be essential for neutralizing the acidic groups of the active ingredients and the gel structure formers (i.e. carbomers), and adjusting the pH of the composition (see column 9, lines 1-9). Additional components such as chemical stabilizers may or may not be present as claimed in the instant claim 30 (see column 8, lines 35-39). Anti-fungal agents are not listed as a possible optional constituent.

Asche et al. does not teach a specific example where the components are within the claimed ranges. However, it would have been obvious to one of ordinary skill at the time of the invention to utilize the broad teachings of Asche et al. to formulate the claimed compositions. In this case, where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976).

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Asche et al. (US 4,917,886) as applied to claims 15-23 and 25-30 above, and in further view of Sekine et al. (US 6,054,484) as evidenced by Krzysik (US 5,399,342).

The teachings of Asche et al. pertaining to the instant claims 15-23 and 25-30 are discussed above. Claim 24 additionally requires the composition of the instant claim 15 to be devoid of C_2-C_4 alkanols.

Asche et al. does not teach a composition that is devoid of a C_2-C_4 alkanols.

Sekine et al. teaches compositions that do not contain lower alkanols where diclofenac sodium is dissolved in water with the aid of coconut fatty acid diethanolamide (see column 2, lines 24-37, and specifically column 10, Example I-4). Coconut fatty acid diethanolamide is a nonionic surfactant as evidenced by Krzysik (see column 11, line 57 to column 12, line 8).

It would be obvious to one of ordinary skill in the art at the time of the invention, to formulate the compositions of Asche et al. without a C_2-C_4 alkanol by using a coconut fatty acid diethanolamide as the nonionic surfactant to aid in the dissolution of diclofenac sodium in water as taught by of Sekine et al. The motivation to remove the lower alkanol is that it causes irritation to the skin, and its volatility makes it unsuitable for medicinal products (see Sekine et al., column 1, line 61 to column 2, line 3).

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571) 274-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

JLK

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER